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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,278	04/09/2002	Susanne Kessler	1951	9010

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103 East Neck Road
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EXAMINER

STITZEL, DAVID PAUL

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/030,278

Applicant(s)

KESSLER ET AL.

Examiner

David P. Stitzel, Esq.

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13, 15-18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 15-18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicant's Request for Continued Examination, Response and Amendment, which was filed on October 3, 2006, in response to the Official Action dated April 19, 2006, is acknowledged.

Status of Claims

Claims 1-9 were canceled, and claims 10-20 were added, by an amendment filed on March 25, 2004. In addition, claims 10-11 and 16-17 were amended, and claims 21-24 were added, by an amendment filed on November 12, 2004. In addition, claims 10-13, 19, 21 and 22 were amended, by an amendment filed on November 1, 2005. Furthermore, claims 14 and 19 were cancelled, and claims 10, 13, 15, 16, 18, 20 and 21 were amended by the aforementioned Amendment filed on October 3, 2006. As a result, claims 10-13, 15-18 and 20-24 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

1. The rejection of claims 13, 14 and 19 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is hereby withdrawn in light of Applicants' amendment to claim 13, and cancellation of claims 14 and 19.

Claim Rejections - 35 U.S.C. § 102

1. The rejection of claims 10-14 and 21-24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,290,544 (the Shimono '544 patent) is hereby withdrawn in light of Applicants' amendment to independent claims 10 and 21, and cancellation of claim 14.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 15 and 20 under 35 U.S.C. § 103(a) as being unpatentable over the Shimono '544 patent in view of the International Application Publication Number WO 98/11853 (the Greenspan '853 publication) is hereby withdrawn in light of Applicants' amendment to independent claims 10 and 16, upon which claims 15 and 20 are respectively dependent.

2. The rejection of claims 16-19 under 35 U.S.C. § 103(a) as being unpatentable over the Shimono '544 patent, in further view of: Yamanaka et al., "Enzymatic Activity of Glucose Oxidase Encapsulated in Transparent Glass by the Sol-Gel Method," *Chemistry of Materials*, 4(3):495-497 (1992) (the Yamanaka publication); Wu et al., "Bacteriorhodopsin Encapsulated in Transparent Sol-

Gel Glass: A New Biomaterial," Chemistry of Materials, 5(1):115-120 (1993) (the Wu publication); and Wang et al., "Affinity of Antifluorescein Antibodies Encapsulated Within a Transparent Sol-Gel Glass," Analytical Chemistry, 65(19):2671-2675 (1993) (the Wang publication) is hereby withdrawn in light of Applicants' amendment to independent claim 16, and cancellation of claim 19.

3. Claims 10-13, 15 and 21-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over International Application Publication Number WO 98/11853 (the Greenspan '853 publication) in view of U.S. Patent 5,290,544 (the Shimono '544 patent).

With respect to claims 10-13, 15 and 21-24 of the instant application, the Greenspan '853 publication teaches a method of protecting skin from infection comprising topically applying to said skin an effective amount of a particulate bacteriostatic bioactive glass composition comprising: 40-60 wt. % SiO₂; 10-30 wt. %, preferably 24.5 wt. %, CaO; 10-35 wt. % Na₂O; 2-8 wt. %, preferably 6 wt. %, P₂O₅; 0-25 wt. % CaF₂; 0-10 wt. % B₂O₃; 0-8 wt. % K₂O; 0-5 wt. % MgO; and a pharmaceutically acceptable carrier, such as an ointment, white petroleum, mineral oil, and/or other pharmaceutically acceptable carriers well known to those of ordinary skill in the art; wherein said particulate bacteriostatic bioactive glass composition has particle diameters of less than or equal to 90 μm, less than or equal to 10 μm, and less than or equal to 2 μm (abstract; page 1, paragraph 1, lines 3 and 4; page 3, paragraph 2, lines 1-3; page 9, paragraph 1, lines 1-5; page 10 in its entirety; page 11, lines 1 and 2, paragraph 1, lines 1-5, paragraph 3, lines 1-5; page 12, paragraph 3, lines 1-13; claims 1-5, 7-9 and 16).

With respect to the newly added recitation within claims 10 and 21 that said particulate bacteriostatic bioactive glass composition comprises CaO and P₂O₅ in an amount such that the molar ratio of calcium to phosphorus is greater than 2, calcium has a molecular weight of approximately

40.078 and phosphorus has a molecular weight of approximately 30.974 and as a result, a particulate bacteriostatic bioactive glass composition comprising four calcium atoms (i.e., four CaO molecules), for every two phosphorus atoms (i.e., one P₂O₅ molecule) would yield a molar ratio of calcium to phosphorus of approximately 2.6, which is greater than 2 as instantly claimed. As previously discussed, CaO and P₂O₅ are present in a preferred embodiment of the particulate bacteriostatic bioactive glass composition of the Greenspan '853 publication in an amount of 24.5 wt. % and 6 wt. %, respectively, which yields a molar ratio of calcium to phosphorus of approximately 4.08, which is greater than 2 as instantly claimed. As a result, the Greenspan '853 publication reads on the newly added claim limitation within claims 10 and 21 that said particulate bacteriostatic bioactive glass composition comprises CaO and P₂O₅ in an amount such that the molar ratio of calcium to phosphorus is greater than 2.

The Greenspan '853 publication does not explicitly teach a method of preserving a perishable cosmetic preparation in the form of a skin cream, skin lotion, make-up or lipstick, wherein said method comprises adding to said perishable cosmetic preparation an effective amount of up to 3 wt. %, up to 7 wt. %, up to 10 wt. %, and up to 25 wt. % of said particulate bacteriostatic bioactive glass composition, as claimed in claims 10, 11 and 21-24. Although it should be mentioned however that the claim recitations of up to 3 wt. %, up to 7 wt. %, up to 10 wt. % and up to 25 wt. %, as claimed in claims 10, 11 and 21-23, reads on a perishable cosmetic preparation comprising 0 wt. % particulate bacteriostatic bioactive glass composition, and thus said perishable cosmetic preparation need not necessarily contain any particulate bacteriostatic bioactive glass whatsoever.

Nevertheless, the Shimono '544 patent teaches a method of preserving a cosmetic preparation in the form of a skin lotion (skin cream is a species within the genus of skin lotion), make-up (i.e., foundation and eye shadow) and lipstick, wherein said method comprises adding to said cosmetic

preparation an effective amount of from about 0.5 to about 2.5 wt. % of a particulate bactericidal bioactive glass composition; wherein said particulate bactericidal bioactive glass composition may comprise: SiO_2 ; CaO ; Na_2O ; P_2O_5 ; K_2O ; and/or MgO ; wherein said particulate bactericidal bioactive glass composition has particle diameters of less than or equal to about 20 μm , preferably less than or equal to about 10 μm , and more preferably less than or equal to about 5 μm (abstract; column 1, lines 6-16, 38-41 and 46-53; column 2, lines 3-64; column 3, lines 3-11, 36 and 47; column 4, lines 18 and 32; column 5, line 33; column 6, lines 17 and 33; column 7, lines 9 and 27; claims 1 and 3-6).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to incorporate the particulate bacteriostatic bioactive glass composition taught by the Greenspan '853 publication, into a cosmetic preparation, as reasonably taught by the Shimono '544 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate the particulate bacteriostatic bioactive glass composition of the Greenspan '853 publication into a cosmetic preparation, so as to preserve said cosmetic preparation by imparting bactericidal protection against invading bacteria that are associated with the outer epithelial tissue layer of the skin and introduced into said cosmetic preparation by a consumer during repeated usage of said cosmetic preparation, as reasonably suggested by the Shimono '544 patent. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success at preserving said cosmetic preparation by imparting bactericidal properties to said cosmetic preparation, via the addition of the particulate bacteriostatic bioactive glass composition of the Greenspan '853 publication, since the particulate bactericidal bioactive glass composition of the Shimono '544 patent may, similar to the particulate bacteriostatic bioactive glass composition of the Greenspan '853 publication, likewise comprise: SiO_2 ; CaO ; Na_2O ; P_2O_5 ; K_2O ; and/or MgO .

4. Claims 16-18 and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Greenspan '853 publication in view of the Shimono '544 patent, and in further view of *either*: Yamanaka et al., "Enzymatic Activity of Glucose Oxidase Encapsulated in Transparent Glass by the Sol-Gel Method," Chemistry of Materials, 4(3):495-497 (1992) (the Yamanaka publication); Wu et al., "Bacteriorhodopsin Encapsulated in Transparent Sol-Gel Glass: A New Biomaterial," Chemistry of Materials, 5(1):115-120 (1993) (the Wu publication); *or* Wang et al., "Affinity of Antifluorescein Antibodies Encapsulated Within a Transparent Sol-Gel Glass," Analytical Chemistry, 65(19):2671-2675 (1993) (the Wang publication).

The teachings of the Greenspan '853 publication and the Shimono '544 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to independent claim 16, neither the Greenspan '853 publication nor the Shimono '544 patent explicitly teach that said particulate bacteriostatic bioactive glass composition has a refractive index sufficiently close to that of said pharmaceutically acceptable carrier so that said particulate bacteriostatic bioactive glass composition is substantially transparent, and thus invisible to a consumer, within said cosmetic preparation.

However, the Yamanaka publication (page 495, column 1, paragraph 1, line 2; page 497, column 1, paragraph 2, lines 1, 16 and 17), the Wu publication (abstract, line 2; page 115, column 1, paragraph 1, lines 2 and 3; page 120, column 2, paragraph 2, lines 2 and 3), and the Wang publication (page 2871, column 2, paragraph 2, line 3), teach bioactive glass particles having a refractive index sufficient to impart a physical property of transparency to said bioactive glass particles.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the instant application was filed to modify the particulate bacteriostatic bioactive glass composition of the Greenspan '853 publication in a manner such that said particulate bacteriostatic bioactive glass

composition, which is to be incorporated into a cosmetic preparation as reasonably taught by the Shimono '544 patent, has a refractive index sufficiently close to that of said pharmaceutically acceptable carrier so as to impart a transparent, and thus substantially invisible and undetectable, physical property to said particulate bacteriostatic bioactive glass composition, as reasonably taught by either the Yamanaka publication, the Wu publication, or the Wang publication. A manufacturer of cosmetic preparations would immediately recognize the benefit of producing a particulate bacteriostatic bioactive glass composition that is more aesthetically pleasing in appearance to conscientious cosmetic consumers by making the particulate bacteriostatic bioactive glass composition, which are contained within said cosmetic composition, substantially invisible and undetectable. As a result, motivation and economic incentive exists for a manufacturer of a cosmetic preparation to modify the refractive index of the particulate bacteriostatic bioactive glass composition contained therein, so as to match the refractive index of said pharmaceutically acceptable carrier and thereby impart transparency to said particulate bacteriostatic bioactive glass composition, thus rendering said particulate bacteriostatic bioactive glass composition, which are present within said cosmetic composition, substantially invisible and undetectable to conscientious cosmetic consumers.

Conclusion

Claims 10-13, 15-18 and 20-24 are rejected because the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, would have been reasonably suggested by the teachings of the cited prior art references.

Examiner's Response to Applicant's Remarks

Although Applicants' arguments as set forth in the aforementioned Response have been fully considered in light of the claims as currently amended, they are not persuasive. Applicant's claim

amendments and the addition of claims 50-100 necessitated the new grounds of rejection as set forth hereinabove.

1. 35 U.S.C. § 102(b) rejection of claims 10-14 and 21-24 based on the Shimono '544 patent.

Applicants' arguments are moot in view of the withdrawal of the aforementioned rejection.

2. U.S.C. § 103(a) rejection of claims 15 and 20 based on the Shimono '544 patent in view of the Greenspan '853 publication.

Applicants' arguments are moot in view of the withdrawal of the aforementioned rejection.

3. U.S.C. § 103(a) rejection of claims 16-19 based on the Shimono '544 patent in view of either the Yamanaka publication, the Wu publication, or the Wang publication.

Applicants' arguments are moot in view of the withdrawal of the aforementioned rejection.

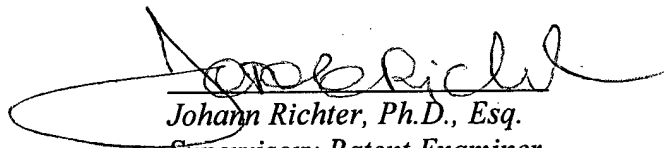
Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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